UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419
THIS DOCUMENT RELATES TO:	)	Dkt. No 1:13-md-2419 (RWZ)
ALL CASES	)	

SAINT THOMAS ENTITIES' MEMORANDUM IN SUPPORT OF THEIR MOTION TO COMPEL AMERIDOSE LLC TO PRODUCE DOCUMENTS REQUESTED IN THEIR SECOND REQUEST FOR PRODUCTION

The Saint Thomas Entities[1] file this Memorandum in Support of their Motion to Compel Ameridose LLC to Produce Documents Requested in their Second Request for Production and respectfully show as follows:

BACKGROUND

The Court previously detailed the claims and defenses at issue in this matter in ruling on several motions for protective orders.[2] The Saint Thomas Entities hereby incorporate that background by reference into this Memorandum. In that Order, the Court stated it needed more information regarding the dispute since the Saint Thomas Entities had not specifically addressed the propriety of Ameridose's objections to each of the document requests. Accordingly, the Court denied the Saint Thomas Entities' motion to compel without prejudice to being refiled.[3] The Saint Thomas Entities now provide such additional details and, for the reasons stated below,

[1] Saint Thomas West Hospital f/k/a St. Thomas Hospital, Saint Thomas Network, and Saint Thomas Health.

[2] *See* Memorandum and Order, issued July 31, 2015 [Dkt. 2123] (hereafter "Protective Order") at pp. 2 to 9.

[3] *Id.* at p. 20, fn. 14.

request that the Court grant their motion and compel Ameridose to produce the documents they have requested.[4]

Ameridose was managed by Gregory Conigliaro and Barry Cadden, the former managers of NECC. According to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, Ameridose was a "distribution center to entities of common ownership – currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

The Saint Thomas Entities are seeking discovery to prove that Ameridose was negligent in its role as NECC's distribution center and in its participation in the design and management of the cleanrooms in which the contaminated MPA was later compounded. From 2006 to 2009, Ameridose occupied the facility that NECC occupied in the fall of 2012 when it compounded contaminated MPA.[5] Documents produced in this litigation reveal that Ameridose communicated extensively with Liberty Industries, Inc. ("Liberty") in constructing the very cleanroom in which the MPA at issue was compounded. An automatic pass-through conveyor belt, which is very much at issue in this litigation, was built by Liberty for Ameridose in 2007. Ameridose was heavily involved in the design process, proposing multiple ways to get product out of the NECC cleanroom more quickly.[6] Moreover, documents show that the management of NECC and Ameridose were intertwined; letters were signed by Steve Higgins, Project Manager

[4] Ameridose LLC's Responses to Saint Thomas Entities' Second Set of Requests for Production ("Ameridose Responses"), attached hereto as Exhibit 1.

[5] *See* Cleanroom Certifications issued to Ameridose, attached hereto as Exhibit 2.

[6] *See* Correspondence and purchase order, attached hereto as Exhibit 3.

for "Ameridose/NECC."[7] In fact, as explained below, the close relationship between the companies impacted regulatory decisions at NECC.

In support of their comparative fault affirmative defenses, the Saint Thomas Entities intend to prove that Ameridose owed an independent duty to Plaintiffs in this litigation and breached it. They also seek discovery from Ameridose regarding NECC and its principals in support of their defense—regardless of which state's laws applies to the Saint Thomas Entities' defenses—that NECC is the sole proximate cause of Plaintiffs' damages.

ARGUMENT AND AUTHORITIES

Ameridose asserted essentially the same stock objections to every document request made by the Saint Thomas Entities.[8] Accordingly, the Saint Thomas Entities will first address the relevance of their requests and then the objections made.

I. THE SAINT THOMAS ENTITIES HAVE REQUESTED RELEVANT, DISCOVERABLE DOCUMENTS

Federal Rule of Civil Procedure 26(b)(1) provides:

> Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense—including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter. For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action. Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence. All discovery is subject to the limitations imposed by Rule 26(b)(2)(C).

The United States Supreme Court has further held that the limits set forth in Rule 26 must be "construed broadly to encompass any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case."[9]

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[7] *See* Letter (undated), attached hereto as Exhibit 4.

[8] *See generally* Ameridose Responses, Ex. 1.

Plaintiffs allege injuries and death based on contaminated epidural injections manufactured and sold by NECC. Plaintiffs are attempting to hold the Saint Thomas Entities liable for these injuries because Saint Thomas Network owns one-half of Saint Thomas Outpatient Neurosurgical Center, LLC ("STOPNC"), an outpatient ambulatory surgery center where NECC product was administered.[10] Plaintiffs allege that STOPNC is liable because it failed to undertake sufficient due diligence before purchasing medication from NECC.[11] In addition to contesting that STOPNC should not have purchased NECC medication, the Saint Thomas Entities allege that other parties are partially or solely responsible for Plaintiffs' injuries – such as NECC and other parties with whom Plaintiffs have already settled for tens of millions of dollars.[12] Ameridose is one such settling party.

The document requests fall into the following subject matters:

- Documents concerning how MPA was compounded by NECC and the potential sources of contamination (Requests 1, 2, 3, 4, 6, 9, 14 and 16);
- The personnel files for the key witnesses (Request 5);
- Placing orders with patient lists (Requests 6 and 14);
- The regulatory failures by the FDA leading to the contamination, as identified by the U.S. Congress (Requests 6, 8, 9, 14);
- NECC's marketing practices and the amount and type of due diligence typically performed by NECC customers (Requests 7, 14); and

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[9] *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978).

[10] *See* Mem. of Decision (August 29, 2014) [Dkt. 1360] at pp. 45-46.

[11] *Id.* at pp. 37-38.

[12] *See* Protective Order at pp. 8-9.

- The design and construction of the NECC cleanroom, including Ameridose's participation in the process (Requests 10, 11, 12 and 13).

These categories are all highly relevant to the claims and defenses in this proceeding. The Saint Thomas Entities seek documents relating to the compounding of MPA by NECC or the contamination of the MPA or any NECC cleanrooms.[13] Whether considered comparative fault or sole proximate cause, the Saint Thomas Entities are entitled to defend themselves by showing that other persons or entities partially or solely caused the contamination at issue, which in turn caused Plaintiffs' injuries. To establish this at trial, they need to discover details regarding how NECC compounded MPA and the contamination of NECC cleanrooms (whether it be historical contamination problems or the contamination that existed during the summer of 2012). It is only by obtaining these two categories of information that the Saint Thomas Entities can provide evidence at trial on who is at fault for the MPA contamination.

The Saint Thomas Entities continue to seek discovery on who compounded MPA at NECC, how it was compounded, the equipment used, the procedure used, and the like. Much of the information goes not only to comparative fault, but also to the issue of what due diligence, if any, would have discovered the contamination prior to the distribution of tainted medication. With respect to other product contamination or recalls, this is relevant to the Saint Thomas Entities' allegations against NECC (its internal knowledge of deficient practices), the regulators (who failed to take sufficient regulatory action against it or warn the public), and the issue of causation (since causes of contamination can be reoccurring).

The Saint Thomas Entities seek the personnel files for Barry Cadden, Lisa Cadden, Greg Conigliaro, Doug Conigliaro and Glenn Chin. These five witnesses are at the center of the

[13] Ameridose Responses, Ex. 4, at p. 4.

meningitis outbreak. Indeed, four have been indicted for their conduct leading to the contamination. Where an employee is "directly involved with the incident giving rise to the action" or "played an important role in the decision or incident that gave rise to the lawsuit," his or her personnel file is discoverable.[14] While some courts outside of the First Circuit have required a "heightened" showing of relevance to obtain an employee file,[15] that standard is met here too. Four of these witnesses have been protected from deposition for the time being due to Fifth Amendment issues, meaning the Saint Thomas Entities cannot ask them under oath about their work history, including disciplinary record for performance issues (such as improper compounding techniques, improper cleaning, etc.).

Discovery against Ameridose regarding its regulatory history is particularly important and appropriate. As the Congressional investigation the Court previously addressed concluded, the FDA's "inaction in the face of years of complaints and red flags associated with the safety of ***both companies' products and underlying practices*** [*i.e.* both NECC and Ameridose] had a tragic ending."[16]

The design of the NECC cleanrooms is highly relevant. As this Court is aware, an expert on cleanroom design and construction has already concluded it was defects in NECC's ceiling that was one cause of product contamination. Discovery to date has revealed that Ameridose

[14] *See, e.g., Vazquez-Fernandez v. Cambridge College, Inc.*, 269 F.R.D. 150, 159 (D.P.R. 2010), citing *Moss v. Blue Cross Blue Shield of Kansas, Inc.*, 241 F.R.D. 683, 698 (D. Kan. 2007).

[15] *See, e.g., Fritz v. Charter Twp. of Comstock*, 2010 U.S. Dist. LEXIS 45260, *5 (W.D. Mich. May 10, 2010) ("When the subject of a discovery request is personnel files, it is appropriate for the Court to require a heightened showing of relevance and need.")

[16] Protective Order at p. 5 (emphasis added).

was not only in charge of the design and construction of the room where the MPA was compounded, but actually operated in the room during its first few years of use.[17]

Finally, NECC's marketing practices are highly relevant, since it was through marketing that NECC assured customers that its products were safe, adequately tested, and met all USP requirements for high quality preparations. The evidence to date shows that NECC and Ameridose jointly marketed their products and worked closely together. Indeed, e-mail correspondence reveals that Ameridose and NECC coordinated their efforts to market product at Saint Thomas Hospital.[18]

The Saint Thomas Entities have sought a limited number of highly relevant documents. As explained below, Ameridose has no legitimate grounds to avoid producing the information requested.

II. AMERIDOSE'S OBJECTIONS ARE GROUNDLESS

Ameridose asserted certain "general" objections and then asserted the same basic, stock objection to every document request. It refused to produce anything. Accordingly, the Saint Thomas Entities address the merits of each objection by subject matter below.

Ameridose appears to argue that it is protected from comparative fault discovery because Ameridose never compounded the MPA at issue and accordingly "cannot be held liable or considered at fault under Tennessee products liability law."[19] First, Plaintiffs have not limited their claims against STOPNC to products. They have also asserted negligence claims, which are

[17] *See* Exhibits 2, 3 and 4.

[18] *See* E-mail chain from April 18, 2012 to April 20, 2012, attached hereto as Exhibit 5 (redacted).

[19] Ameridose Responses, Ex. 1, at p. 2.

clearly subject to comparative fault under Tennessee law.[20] Moreover, the Tennessee Supreme Court has held that "comparative negligence applies to products liability actions based on strict liability in tort."[21] Indeed, Ameridose even cites the seminal case explaining "the rights and liabilities between multiple defendant in a strict liability action," *Owens v. Truckstops of America, Inc.*[22] There, the Tennessee Supreme Court explained:

> When liability is found on strict liability and also negligence or other theories, the trier of fact must apportion the fault for the plaintiff's injuries or damages according to the percentage of damages caused by the plaintiff, that caused by the product, and that caused by each tortfeasor acting separately and independently.[23]

The Court even outlined in a footnote the special verdict form to be used where liability is predicated "upon strict products liability and other theories such as negligence."[24] Discovery of Ameridose's negligence in causing or contributing to the contamination – such as its actions in designing and installing the NECC cleanroom and the "temporary" pass-through and conveyor belt inside of the main cleanroom – is clearly permissible here.

Ameridose next argues that discovery is not permitted against it because none of the claims alleged by Plaintiffs and/or against Saint Thomas Entities relate to or implicate Ameridose. It concludes this by asserting that it did not "manufacture, compound, test, or distribute" the MPA at issue. If that were the test, then UniFirst, Liberty, Victory and ARL BioPharma would likewise have escaped any and all discovery obligations. They did not, because the argument is frivolous. First and foremost, Ameridose participated in the

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[20] *See supra,* note 10; *see generally Owens v. Truckstops of America, Inc.,* 915 S.W.2d 420, 433 (Tenn. 1996) (explaining that comparative fault applies to strict liability claims as well as ordinary negligence claims).

[21] *Whitehead v. Toyota Motor Corp.,* 897 S.W.2d 684 (Tenn. 1995).

[22] Ameridose Responses, Ex. 1, at p. 2.

[23] *Owens v. Truckstops of America, Inc.*, 915 S.W.2d 420, 433 (Tenn. 1996).

[24] *Id.* at 433, fn. 17.

construction and initial operation of the cleanroom where the contaminated MPA was compounded. Second, the close relationship between the companies and overlapping ownership and management makes it highly likely that it possesses information regarding NECC. The Saint Thomas Entities are entitled to seek and obtain discovery from Ameridose supporting their claims against NECC.

Finally, Ameridose's attempt to insinuate it had nothing to do with NECC is belied by the fact it too was shut down alongside NECC. Or as a committee report from the United States Congress explains:

> Ameridose, had a significant history with FDA. FDA was well aware of the ***firms' shared ownership and management***. On several occasions, ***this factored into FDA's decision-making*** about whether and when to take certain actions related to one of the companies.[25]

Ameridose's objection that the requests are duplicative of prior requests is likewise groundless. It is because Ameridose objected to the prior requests that the Saint Thomas Entities attempted to narrow and clarify the documents it sought. Ameridose's response to such effort made it clearer than ever that nothing would ever be produced absent this Court's order.

Ameridose next objects that it would be prohibitively expensive to conduct searches for electronically stored information. Of course, this Court already addressed that issue by entering an ESI Protocol that addressed document sources, custodian limitations and search terms. Accordingly, when Ameridose disclosed to the Saint Thomas Entities that it had not processed ***all of the hard drives that exist*** and that doing so would be unduly burdensome and expensive, the Saint Thomas Entities proposed a common sense solution per the ESI protocol:

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[25] See FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities, Staff Report, Committee on Energy and Commerce, April 16, 2013 (emphasis added), available at http://docs.house.gov/meetings/IF/IF02/20130416/100668/HHRG-113-IF02-20130416-SD101.pdf.

> While we cannot agree at this time to limit search terms to the e-mail server, ***we are open to the discussion***. In particular, please provide us with an index or listing of the hard drives you possess along with any information you have on the source, custodian and content of each drive ***so that we can determine which of the hard drives the Saint Thomas Entities will agree to exclude from the search terms we hopefully can agree upon.***[26]

The Saint Thomas Entities even provided a list of search terms to minimize the cost and burden of the document production.[27] Ameridose refused to do provide any of the information requested or search its e-mail servers, which have already been imaged and are easily searchable. It has not only refused to comply with the ESI Protocol, it has provided this Court with no evidence that it would be unduly burdensome to comply with the Saint Thomas Entities' suggested limitations.

Ameridose also objects that it "cannot speak to the business operations of NECC." Of course, the Saint Thomas Entities have not asked it to do so. They have asked it to produce documents within its possession, custody or control regarding NECC's business operations. It next "objects" that it had its own cleanrooms. That is true. They are the cleanrooms the FDA was inspecting alongside with NECC's when it made its joint regulatory decisions regarding the companies.

Ameridose objects that its correspondence with Liberty (which designed and installed NECC's cleanrooms) "can be obtained from some other source that is more convenient, less burdensome, or less expensive." This objection lacks merit. First, the Saint Thomas Entities have sought the documents that Liberty maintained from its projects with NECC and Ameridose. However, Liberty cannot produce the e-mails and documents Ameridose kept relating to those projects. Documents produced by Liberty are also not self-authenticating as to Ameridose. And

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[26] *See* Letter from Adam Schramek to Matthew Moriarty dated April 16, 2015, attached hereto as Exhibit 6 (emphasis added).

[27] *Id.*

nobody but Ameridose possesses Ameridose's internal e-mails relating to the projects. For example, Liberty could not explain at its deposition why during the middle of its construction of the cleanroom where the contaminated MPA was compounded, Ameridose instructed Liberty to use the name "Ameridose" on the project instead of NECC on a going forward basis.[28]

CONCLUSION

Rather than participate in discovery in good faith and in compliance with this Court's ESI Protocol, Ameridose asserts groundless objection after groundless objection. The time has come for the gamesmanship to end. The Saint Thomas Entities respectfully request that the Court compel Ameridose to produce all documents they have requested.

[28] *See* E-mail dated April 24, 2006, attached hereto as Exhibit 7.

SAINT THOMAS WEST HOSPITAL, FORMERLY KNOWN AS ST. THOMAS HOSPITAL, SAINT THOMAS NETWORK, AND SAINT THOMAS HEALTH

By their attorneys,

/s/ Sarah P. Kelly

Sarah P. Kelly (BBO #664267)
skelly@nutter.com
NUTTER McCLENNEN & FISH LLP
Seaport West
155 Seaport Boulevard
Boston, Massachusetts 02210
(617) 439-2000
(617) 310-9461 (FAX)

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OF COUNSEL:

Yvonne K. Puig*
Texas State Bar No. 16385400
Adam T. Schramek*
Texas State Bar No. 24033045
Eric J. Hoffman*
Texas State Bar No. 24074427

Norton Rose Fulbright US LLP
98 San Jacinto Blvd. Suite 1100
Austin, Texas 78701
(512) 536-2450
(512) 536-4598 (FAX)

Marcy Hogan Greer*
Texas State Bar No. 08417650
mgreer@adjtlaw.com

ALEXANDER DUBOSE JEFFERSON & TOWNSEND LLP
515 Congress, Suite 2350
Austin, Texas 78701
(512) 482-9300
(512) 482-9303

*Appearing *Pro Hac Vice*

CERTIFICATE OF SERVICE

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 25th day of August, 2015.

/s/ Sarah P. Kelly
SARAH P. KELLY

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